REMARKS

The Office Action of May 21, 2004, has been received and reviewed. Claims 1-12 and 14-22 are pending of which claims 4-10, 12, 14, 15, 18 and 19 are withdrawn from consideration. Claims 21 and 22 stand allowed, and claims 1-3, 11, 16, 17 and 20 stand rejected. Claims 1, 2, 11, 16, 17 and 20 have been amended, claim 3 has been canceled and new claims 23-27 have been added as set forth herein. All amendments and cancellations are made without prejudice or disclaimer. Reconsideration is requested.

Rejections under 35 U.S.C. § 102

Claims 1-3 and 20

Claims 1-3 and 20 stand rejected under 35 U.S.C. § 102(b) as assertedly being anticipated by Bilej et al. Claim 3 has been canceled rendering the rejection thereof moot. Applicants respectfully traverse the rejections.

Claim 1 is directed to an isolated peptide which has from 13 to 60 amino acids, and which comprises SEQ ID NO: 1, wherein the isolated peptide possesses trypanolytic activity as determined by a trypanolytic assay. In formulating the asserted anticipation rejections, the Office Action stated that "there is nothing on the record to show why the peptide of the reference is not the same as the claimed peptide." (Office Action, page 3). However, the peptide of claim 1 is from 13 to 60 amino acids in length (*i.e.*, the claimed peptide is not longer than 60 amino acids). Bilej et al. (March-April 1994) does not expressly or inherently disclose a protein that is not longer than 60 amino acids. Bilej et al. discloses "a semi-pure active fraction" which includes **full-length** proteins and not proteins that are shorter than 60 amino acids. (*See*, Bilej et al., March-April 1994). Thus, Bilej et al. does not identically disclose the isolated peptide of claim 1.

Claim 2 also cannot be anticipated since Bilej et al. does not identically disclose an isolated or recombinant peptide comprising the amino acid sequence of SEQ ID NO: 3 or a fragment thereof having trypanolytic activity as determined by a trypanolytic assay as recited in claim 2. For instance, Bilej et al. does not identically disclose an isolated peptide comprising the amino acid sequence of SEQ ID NO: 3. The Office Action indicated "it should be noted that monoclonal antibodies were prepared from the semi-purified fraction of Bilej et al. It is not

known in the art to prepare monoclonal antibodies to fractions that are not pure or peptides that have not been isolated." (Office Action at page 3).

However, Bilej et al. clearly indicates that "a **semi-pure** fraction was used to prepare monoclonal antibodies (mAb) that were screened for neutralizing the cytolytic effects of the coelomic fluid." (Bilej et al.) (*emphasis added*). Thus, Bilej et al. is limited to the **semi-pure** fraction and does not disclose any **isolated** protein. The Federal Circuit has indicated that claiming a compound in its pure and isolated form is one way that a skilled patent drafter may fashion a claim in order to avoid anticipation. (*See*, Schering Corp. v. Geneva Pharmaceuticals, Inc., 339 F.3d 1373, 1381, 67 USPQ2d 1664, 1672 (Fed. Cir. 2003)). Thus, the isolated peptides of claim 2 distinguish over the semi-pure fraction Bilej et al. Further, Bilej et al. does not identically disclose any **recombinant** peptides and, thus, cannot anticipate a recombinant peptide as recited in claim 2. Accordingly, claim 2 cannot be anticipated.

With regard to claim 20, it cannot be anticipated since Bilej et al. does not identically disclose an isolated or recombinant peptide having a sequence selected from the group consisting of SEQ ID NO: 1, an amino acid sequence which has from 13 to 60 amino acids and which comprises SEQ ID NO: 1, a recombinant amino acid sequence comprising SEQ ID NO: 3, and a fragment of the recombinant amino acid sequence comprising SEQ ID NO: 3 having trypanolytic activity as determined by a trypanolytic assay. As previously established herein, Bilej et al. is limited to a "semi-pure active fraction" and, thus, cannot anticipate any isolated or recombinant peptide.

Reconsideration and withdrawal of the anticipation rejections of claims 1-2 and 20 are requested.

Claims 11 and 16-17

Claims 11 and 16-17 stand rejected under 35 U.S.C. § 102(b) as assertedly being anticipated by Bilej et al. Applicants respectfully traverse the rejections as set forth herein.

Bilej et al. (Immunology Letters) cannot anticipate claim 11 since Bilej et al. does not identically disclose a composition comprising a peptide selected from the group consisting: an isolated peptide which has from 13 to 60 amino acids and which comprises SEQ ID NO: 1,

wherein the isolated peptide possesses trypanolytic activity as determined by a trypanolytic assay; an isolated or recombinant peptide comprising SEQ ID NO: 3, wherein the isolated or recombinant peptide possesses trypanolytic activity as determined by a trypanolytic assay; a fragment of either thereof having trypanolytic activity as determined by a trypanolytic assay, and an epitope of either thereof.

The Office Action indicated that "Bilej et al. teach a semi-pure fraction that retains trypanolytic activity. It should be noted that monoclonal antibodies were prepared from the semi-purified fraction of Bilej et al. It is not known in the art to prepare monoclonal antibodies to fractions that are not pure or peptides that have not been isolated." (Office Action at page 5). However, Bilej et al. indicates

> *3.4* ***Semi-purification*** *of the cytolytic fractions of the coelemic fluid*
> Three-times diluted CF sample (3.3 mg/ml) was dialyzed for 3 h in 100 mM TRIS + 1 mM EDTA buffer (pH 8) at 4°C and subjected to ion-exchange chromatography ... dialyzed and concentrated tumoricidal fractions obtained from ion-exchange chromatography was used for intra-food pad immunization of Balb/c mice.

(Bilej et al. at 124) (*emphasis added*). Thus, Bilej et al. clearly indicates that the fractions are **semi-pure**, and not **isolated** or **recombinant** as recited in claim 11. Further, nothing in Bilej et al. indicates that pure fractions were used to prepare monoclonal antibodies. Rather, Bilej et al. indicates that the cytolytic fractions of the coelomic fluid were **semi-purified**. (*See*, *Id.*). Accordingly, claim 11 cannot be anticipated.

Claims 16 and 17 are not anticipated, at the very least, as depending from novel independent claim 11.

Reconsideration and withdrawal of the anticipation rejections of claims 11 and 16-17 are requested.

Rejections under 35 U.S.C. § 112, first paragraph

Written Description

Claims 1 and 3 stand rejected under 35 U.S.C. § 112, first paragraph, as assertedly failing to comply with the written description requirement. Claim 3 has been canceled rendering the rejection thereof moot. Applicants respectfully traverse the rejections.

Specifically, it was thought that the specification has failed to describe the structure of the claimed fragments or epitopes of SEQ ID NO: 1 and SEQ ID NO: 3. (*See*, Office Action at page 7). As an initial matter, the term "epitopes" is not present in claim 1. With regard to fragments, claim 1 is not directed to fragments of SEQ ID NO: 1 or 3, but rather is directed to a peptide of between about 13-60 amino acids and comprising SEQ ID NO: 1. Further, the as-filed specification clearly indicates that the structure of SEQ ID NO: 1, which is 13 amino acids long, possesses trypanolytic activity. (*See*, Specification as-filed, page 17). The as-filed specification further indicates that

> The term "fragment or a sequence" or "part of a sequence" means a truncated sequence of the original sequence referred to. The truncated sequence (nucleic acid or protein sequence) can vary widely in length; the minimum size being a sequence of sufficient size to provide a sequence with at least a comparable function and/or activity of the original sequence referred to, while the maximum size is not critical. In some applications, the maximum size usually is not substantially greater than that required to provide the desired activity and/or function(s) of the original sequence. Typically, the truncated amino acid sequence will range from about 5 to about 60 amino acids in length.

(*Id.* at page 9). Thus, when claim 1 is read in light of the as-filed specification, one of ordinary skill in the art would understand that the inventors were in possession of the claimed invention.

Reconsideration and withdrawal of the written description rejection of claim 1 is requested.

Enablement

Claims 1-3, 11, 16-17 and 20 stand rejected under 35 U.S.C. § 112, first paragraph, as assertedly containing subject matter which was not described in the specification in such a way to enable one skilled in the art or to which it pertains to make and/or use the invention. Claim 3 has been canceled rendering the rejection thereof moot. Applicants respectfully traverse the rejections.

Specifically, it was thought that the applicants have not provided enablement for the genus of peptides claimed. (*See*, Office Action at page 9). However, the as-filed specification would inform one of ordinary skill in the art how to make and use the invention of each of claims 1-2, 11, 16-17 and 20 without undue experimentation. For instance, the specification discloses a

trypanolytic domain of CCF-1 to be SEQ ID NO: 1. (*See*, Specification as-filed page 17). The specification further teaches that a recombinantly produced CCF-1 (e.g., rCCF-1 which comprises SEQ ID NO: 3) is trypanolytic. (*See*, *Id.* at page 21). rCCF-1 was produced by expressing a nucleic acid that encoded rCCF-1. (*See*, *Id.* at pages 20-21).

The specification further discloses

> polypeptides may be generated in any manner, including for example, chemical synthesis, or expression of a recombinant expression system, or isolation form a suitable viral system... it is also understood that the proteins according to the present invention may be further modified by conventional methods known in the art. By providing the proteins according to the present invention, it is also possible to determine fragments which retain biological activity.

(*Id.* at page 9). Thus, one of ordinary skill in the art would be able to make peptides including SEQ ID NO: 1 or fragments of SEQ ID NO: 3 without undue experimentation.

Submitted herewith is a Declaration of Dr. Alain Beschin which further indicates that fragments of SEQ ID NO: 3 and peptides including SEQ ID NO: 1 possess trypanolytic activity. For instance, the Declaration indicates that peptide fragments E3 and E4, each of which include SEQ ID NO: 1 and each of which are fragments of SEQ ID NO: 3, possess trypanolytic activity as determined by a trypanolytic assay commensurate in scope with the as-filed specification. (*See*, Specification as-filed, pages 14-15). Accordingly, one of ordinary skill in the art would be able to make and use the peptides and compositions of the instant invention without undue experimentation.

Thus, claims 1-2, 11, 16-17 and 20 comply with the enablement requirement.

Reconsideration and withdrawal of the enablement rejections of claims 1-2, 11, 16-17 and 20 are requested.

Enablement

Claims 1-3, 11, 16-17 and 20 further stand rejected under 35 U.S.C. § 112, first paragraph, under a new ground for a rejection as assertedly not being enabling for disclosing how the claimed pharmaceutical compositions can be used to treat all microbial infections and cancers. Claim 3 has been canceled rendering the rejection thereof moot. Applicants respectfully traverse the rejections as set forth herein.

As an initial matter, none of claims 1-2 or 20 include the term "pharmaceutical composition." Thus, claims 1-2 and 20 should not be included with the instant rejection.

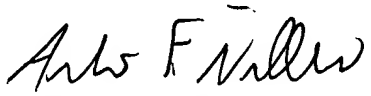
With regard to claims 11, 16 and 17, although applicants do not agree with the enablement rejection since the compositions are shown to exhibit trypanolytic activity (*See, Id.* at pages 21-22) and, thus, may be used as a pharmaceutical composition to lyse trypanosomes, to expedite prosecution the term "pharmaceutical" has been removed from the claims 11, 16 and 17.

Reconsideration and withdrawal of the enablement rejections of claims 1-2, 11, 16-17 and 20 are requested.

CONCLUSION

In view of the foregoing amendments and remarks, applicants respectfully submit that the claims define patentable subject matter and an early notice of allowance is requested. Should questions remain after consideration of the foregoing, the Office is kindly requested to contact the applicants' attorney at the address or telephone number given herein.

Respectfully submitted,



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